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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,043	02/17/2004	Elizabeth Bates	SF0977XB	1489

24265 7590 08/22/2005

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
2000 GALLOPING HILL ROAD
KENILWORTH, NJ 07033-0530

EXAMINER	
CROWDER, CHUN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,043	BATES ET AL.	
	Examiner	Art Unit	
	Chun Crowder	1644	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-16* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

HC

DETAILED ACTION

Restriction Requirement

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, 2 and 6, drawn to an isolated polypeptide and its fusion protein comprising an amino acid sequence derived from SEQ ID NO: 2, 4, 6, 8 or 10, classified in Class 530, subclass 350.

II. Claims 3-5, 10-12, drawn to an isolated nuclei acid molecule comprising SEQ ID No:1, encoding polypeptide of SEQ ID NO:2, 4, 6, 8 or 10, an expression vector, host cells and method of producing the said polypeptide, classified in Class 536, subclasses 23.53; Class 435, subclasses 320.1, 252.3, 325 and 69.1.

III. Claims 7-9, drawn to a binding compound specifically binds to the isolated polypeptide comprising amino acid sequence derived from SEQ ID NO: 2, 4, 6, 8, or 10, classified in Class 530, subclass 387.1.

IV. Claims 13 and 14, drawn to a method for detecting a specific nucleic acid sequence in a sample using probe comprising at least 8 consecutive nucleotides of SEQ ID NO: 1, 3, 5, 7, or 9, classified in Class 435, subclass 6.

V. Claim 15, drawn to a method for detecting a specific antigenic component in a sample using antibody specific for amino acid molecule of SEQ ID NO: 2, 4, 6, 8, or 10, classified in Class 435, subclass 7.1.

VI. Claim 16, drawn to a method of screening for candidate therapeutic agents using a target sequence having an amino acid sequence derived from SEQ ID NO:2, 4, 6, 8, or 10, classified in Class 435, subclass 7.1.

2. Groups I-III are different products. They are different inventions because polypeptide, binding compound to polynucleotide and polynucleotide differ with respect to molecular structures, physiochemical properties and/or mode of action. Further, they require non-coextensive searches in the scientific literature. Therefore, each product is patentably distinct.

3. Groups I/IV-V, II/IV-VI, III/IV, and III/VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the isolated polypeptides and method of detecting nucleic acid sequence, isolated nucleic acid molecules, vector, host cells and method of making polypeptide and method of detecting specific antigenic component and screening for therapeutic agent, binding compounds to an isolated polypeptide and method of detecting polynucleotide are all distinct and not able to be used together. Therefore, each group is patentably distinct.

4. Groups I/VI, II/V, III/IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products as claimed can be used in a materially different process, for example, the polypeptide in can be used for crystallography in addition to method of screening; the isolated polynucleotide molecules can be used in PCR reactions in addition to method of detecting; the binding compounds can be used for affinity purification in addition to the method of detecting and screening.

5. Groups IV-V are different methods. The methods differ with respect to one or more of ingredients, method steps, and/or endpoints. Therefore, each method is patentably distinct. In addition, the distinct ingredients, method steps, and/or endpoints require separate searches. As such it would be burdensome to search these inventions together.

6. These inventions are distinct for the reasons given above. In addition, they have acquired a separated status in the art as shown by different classification and/or recognized divergent subject matter. Even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited. Moreover, a prior art search also requires a literature search. It is an undue burden for an examiner to more than one invention. Therefore, restriction for examination purpose as indicated is proper.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

8. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.*

9. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.
Patent Examiner
August 16, 2005

PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
8/18/05